

## REMARKS

This response is submitted in reply to the Office Action mailed August 4, 2011 ("the Action"). Claims 1, 4, 18, 20, 22, 24, 32, 62, 66, 67, 69, 71 and-72 are pending in the application. Applicant has canceled other claims to advance prosecution and narrow the issues.

### **I. The 112, Second Paragraph Rejection**

The Action notes that there is no antecedent basis for the term "the flexible floor layer" in Claim 4. Applicant has canceled the phrase in this claim.

### **II. Response to Prior Arguments**

The frame in Ede (US 7,588,030) holds injection molded cups that are pushed up to release the respective dose. The Action cites to the alleged advantage of a larger number of doses to be contained for a given surface area (Ede, col. 3, lines 36-40) as the basis for the modification of Snow with the frame of Ede. However, this advantage proposed by Ede is based on deep drawn pockets for inserts.

Ede uses a frame component and insert molded cups. The frames would appear to require straight vertical sidewalls to hold the cups and allow the proper motion. Further, the sidewalls do not contact the dry powder as the dry powder is held in the cup. In Ede, the cup forms a pseudo- (side to side) seal between the sidewalls.

In contrast, in the claimed subject matter, the dry powder contacts the sidewalls and the sidewalls form part of the sealed compartment of the dose container system (DCS). In this design, the component of the DCS with the least resistance to moisture is the frame as the top and bottom sealant (e.g., foil) layers are very good (if not superior) moisture barriers relative to the frame. Providing a thicker frame does not resolve this issue. That is, the sidewall forms a moisture path for each DCS that is not associated with the design of Ede. Introducing larger numbers of dose containers on the frame, even if the frame itself is thicker, further reduces the size of the sidewalls between respective DCSs, which can increase moisture susceptibility.

Snow (US 2002/0134382) proposes a design with an optional center member 108

(para. 88, p. 6). As such, the center member 108 is not required; it would not appear to be part of the DCS. Snow says that the middle layer 108 can be omitted as it is for improving entrainment and delivery. *See, e.g.*, para. 88, p. 6. While the middle layer 108 can have two concentric rows of apertures 152, these are for a single row of DCSs 100 that hold the dry powder in the lower member 112. *See*, para. 70 and 106. Applicant submits that one of skill in the art would not have been motivated to use the frame of Ede with the lower layer of Snow. Snow uses a rigid or semi rigid lower member that forms the DCS; there is no motivation to use a center frame with the thickness and configuration claimed. Indeed, if Snow were to be somehow modified to use the thicker frame of Ede, perhaps the lower member would be made thicker. As the center member 108 is optional and for entrainment, there is no motivation to add in a thick center frame as alleged for increased numbers of doses.

Further, Ede and Snow each have very different opening and sealing configurations. Ede uses integral cup inserts that are injection molded to the frame, while Snow uses a bottom ring with a single row of formed blisters and the bottom member is rigid or semi-rigid (para. 86). The bottom ring also has deep wells, it is not planar (nor flexible). The Action alleges that Snow teaches that the bottom of the lower member is planar. Applicant respectfully disagrees. The bottom ring has an arcuate shape (see the section view shown, for example, in Figures 2A-2C). However, Applicant has amended the independent claims to recite that the floor is defined by a layer or layers of planar flexible sealant material.

The package design is constrained by many factors and affects cost as well as dose filling protocols and opening of the dose containers. Further, the moisture path in the claimed design teaches away from the thicker frame with the two rows of DCSs (as opposed to air entrainment apertures) that directly contact the dry powder.

In addition, the method of blister opening in Snow, piercing two separate holes on the same plane, and the associated flow path, air in one hole and out the other are factors that determine or dominate the number of doses for a given amount of surface area, such that a thicker frame does not help with this configuration, as it may in Ede.

Applicant submits that, even somehow combined as alleged, Ede and Snow fail to teach or suggest a flexible planar lower layer(s), and the thicker frame, particularly when used

with the two concentric rows of DCSs.

Hickey (WO 01/68169) describes circumferentially spaced apart blisters but no intermediate frame (as conceded by the Action, page 5-6). However, the Action again alleges that one of skill in the art would have used the frame of Ede with the blister package of Hickey for a larger number of doses as allegedly taught by Ede. Applicant respectfully disagrees.

The Action cites to the alleged advantage of a larger number of doses to be contained for a given surface area because of the greater depth to width ratio (Ede, col. 3, lines 36-40) as the basis for the modification of Hickey with the frame of Ede. However, this advantage or alleged motivation proposed by Ede is based on deep drawn pockets for inserts where the frame does not form part of the DCS, so it is not a moisture path. Further, the top and bottom layers of Hickey provide better moisture barriers for a respective DCS than the claimed subject matter. To include more blisters, one could simply add another row of blisters in the blister package of Hickey. It is unclear why a thick center platform would be needed to allow the additional numbers or rows of DCSs (particularly where the frame is not for holding injection molded cups or inserts). There is no motivation to modify Hickey as alleged, and particularly using the claimed frame thickness, absent the teachings of the present invention, as doing so would greatly increase moisture susceptibility to respective DCSs. Applicant submits that, even somehow combined as alleged, Ede and Hickey fail to teach or suggest the thicker frame, particularly when used with the two concentric rows of DCSs with sidewalls of the center frame forming part of the DCS (and a moisture path for the dry powder).

### CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, she is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

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**CERTIFICATION OF TRANSMISSION**

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on October 5, 2011.

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